entered a plea of guilty. The defendant Anne M. Jenks, having entered a plea of not guilty, the charges against her were tried to the court. The Government produced no witnesses but evidence was introduced by and on behalf of the defendants. Judgment was entered by the court finding Anne M. Jenks guilty. The court thereupon imposed a fine of $500 against W. S. Jenks and a fine of $250 against Anne M. Jenks. No evidence of any violation of the law by the defendant C. H. Jenks having been introduced, the action against him was dismissed.

753. Misbranding of intrauterine paste. U. S. v. 22 Tubes of Intrauterine Paste (and 9 other seizure actions against intrauterine paste). Default decrees of condemnation and destruction. (F. D. C. Nos. 6564, 6567, 6571, 6574, 6579, 6580, 6590, 6613, 6690, 6745. Sample Nos. 16897–E, 16898–E, 22398–E, 23114–E, 48990–E, 48991–E, 71514–E, 84674–E, 90131–E.)

Between December 26, 1941, and January 22, 1942, the United States attorneys for the Southern District of New York, Western District of Missouri, District of Massachusetts, Northern District of Georgia, and the Northern District of California filed libels against 22 tubes of intrauterine paste at New York, N. Y.; 49 cartons, each containing 1 tube of intrauterine paste at Kansas City, Mo.; 13 tubes at Chillicothe, Mo.; 33 tubes at Medford, Mass.; 27 tubes at Atlanta, Ga.; and 36 tubes at San Francisco, Calif., alleging that the article had been shipped in interstate commerce within the period from on or about September 28, 1941, to on or about January 2, 1942, in part under the name Dependon Products from St. Paul, Minn., and in part under the name Jenks Physicians' Supplies from White Bear Lake, Minn.; and charging that it was misbranded.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling. It was alleged to be misbranded further in that the statement "Intrauterine Paste," borne on the labels, represented and suggested that it would be safe and appropriate for introduction into the uterine cavity; whereas it was not safe or appropriate for introduction into the uterine cavity, but was unsafe and dangerous and was capable of producing serious and even fatal consequences.

On February 27 and 28 and September 28, 1942, no claimant having appeared for the seizures at New York, Kansas City, and Chillicothe, and one of the seizures (involving 6 tubes) at San Francisco, Calif., judgments of condemnation were entered and the product was ordered destroyed in each instance, with the exception of the lot seized at New York, N. Y., which was ordered delivered to the Food and Drug Administration.

On March 12, 1942, Anne M. Jenks, trading as Dependon Products and Jenks Physicians' Supplies, having entered an appearance in the district court for the District of Massachusetts and stipulations having been entered between the claimant and the United States attorney for consolidation of the cases instituted in the District of Massachusetts, the Northern District of Georgia, and the seizure of 30 tubes of Dependon Paste at San Francisco, Calif., and the removal of the cases to the Western District of Wisconsin, the court ordered the consolidation and transfer of said cases as stipulated.

On April 1, 1943, no claim or answer having been filed and the intervener having stipulated that the appearance of counsel be withdrawn and that further proceedings should be had as upon default, judgments of condemnation were entered and the product was ordered delivered to the Food and Drug Administration.

754. Misbranding of Luebert's preparations. U. S. v. 4¾ Dozen Boxes of Luebert's (Nox'em Brand) Iron Tonic Compound Tablets, 2¾ Dozen Boxes of Luebert's Ka-No-Mor Capsules, and 2⅔ Dozen Boxes of Luebert's Noxem Brand Tablets and Capsules (Combined). Default decree of condemnation and destruction. (F. D. C. No. 6837. Sample Nos. 54634–E to 54636–E, incl.)

This case was based upon the following violations: Drugs containing acetanilid and dangerous to health when used with the frequency and duration recommended in the labeling—Ka-No-Mor Capsules and Noxem Brand Tablets and Capsules (Combined); labeling failing to bear adequate warning statements and containing false and misleading therapeutic claims—all three products; failure to bear adequate directions for use—Ka-No-Mor Capsules; failure to bear satisfactory active ingredient statements—Iron Tonic Compound Tablets and Noxem Brand Tablets and Capsules (Combined); and inconspicuousness of warning statement—Ka-No-Mor Capsules.

On or about February 14, 1942, the United States attorney for the District of Delaware filed a libel against the above-named drug preparations at Wilmington, Del., alleging that they had been shipped in interstate commerce on or about May 17 and June 27, 1941, by A. G. Luebert, P. D.; and charging that they were misbranded.

Analysis of Luebert's Iron Tonic Compound Tablets showed that they consisted essentially of salts of iron and manganese, strychnine sulfate, arsenic trioxide, a phosphide, and fish oil. They were alleged to be misbranded: (1) In that the labeling failed to warn against their use by children and by elderly persons because of their strychnine content, and it also failed to warn against taking more than the recommended dose and against frequent or continued use because of their strychnine and arsenic content. (2) In that the statements in the labeling which represented and suggested that they would produce rich blood, good health, strong nerves, and astounding vitality; would give strength and vigor to the entire system; would cleanse the blood after the accumulations of the winter months; would benefit those who are weak, run-down, or depressed; would insure a vigorous condition of the nervous system; would produce proper activity of all the organs and functions of the body; would stimulate the nutritive functions; would act as a general tonic to the digestive tract; would be efficacious for those conditions which call for an effective tonic, such as loss of appetite and a tired run-down feeling; and that they were solely an iron tonic, were false and misleading since they would not produce such effects, and they contained physiologically active drugs in addition to an iron compound. (3) In that they were fabricated from two or more ingredients and their label failed to bear a statement of the quantity or proportion of strychnine sulfate and arsenic trioxide that they contained.

Analysis of the Ka-No-Mor Capsules showed that they contained acetanilid (3 grains per capsule), caffeine, and aspirin. They were alleged to be misbranded: (1) In that they would be dangerous to health when used with the frequency or duration recommended in the labeling. (2) In that the labeling failed to warn against their use by children; and against unsafe dosage or duration of administration since the box labels failed to restrict the number of doses, and although the circular restricted their use to five capsules a day, such use constituted an excessive dosage of acetanilid. (3) In that the directions for use provided for administration of an excessive amount of acetanilid. (4) In that the warning against use in those pathological conditions where their use might be dangerous to health did not appear in the labeling with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use. (5) In that certain statements in the labeling which represented and suggested that when used as directed the capsules constituted a safe and appropriate treatment for the relief of pain and discomfort of simple headache, neuralgias, and muscular aches and pains, for pain following tooth extraction, for helping to allay functional menstrual pains, for common colds, for helping to allay feverish conditions in colds, and for rheumatic pains, were false and misleading since they did not constitute a safe and appropriate treatment for such conditions but were a dangerous drug; and the label failed to reveal the material fact that their use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

Analysis of Luebert's Noxem Brand Tablets and Capsules (Combined) showed that the tablets consisted essentially of sodium salicylate, caffeine, strychnine sulfate, and a laxative plant drug; and that the capsules consisted essentially of acetanilid (3 grains per capsule), aspirin, and caffeine. They were alleged to be misbranded: (1) In that they would be dangerous to health when used with the frequency or duration recommended in the labeling. (2) In that the labeling failed to warn (a) that they should not be given to children because of their acetanilid and strychnine content; (b) that they should not be used by elderly persons because of their strychnine content; (c) that they could not be safely administered over a long period of time because they contained strychnine; (d) that because of their acetanilid content frequent or continued use might result in serious blood disturbances, anemia, collapse, or dependence upon the drug; and (e) against unsafe dosage of an article containing acetanilid and strychnine. (3) In that representations in the labeling that they were an adequate treatment for rheumatic fever and were an appropriate treatment for aches and pains of neuralgia, gout, and muscles, were false and misleading since they would not be efficacious for such purposes. (4) In that the label failed to declare one of the active ingredients under its common or usual name, i. e., aspirin; and to bear a statement of the quantity or proportion of strychnine sulfate that was present.

On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

755. Adulteration and misbranding of Gilmore's Headache Powders. U. S. v. 45 Packages of Gilmore's Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 7354. Sample No. 86370–E.)

This product, in addition to being dangerous to health when used according to directions, failed to bear adequate directions for use and warning statements in the labeling, and contained acetanilid, caffeine citrate, and sodium bicarbonate greatly in excess of the amounts declared on the label.

On April 16, 1942, the United States attorney for the Northern District of Indiana filed a libel against 45 packages of the above-named article at Fort Wayne, Ind., alleging that it had been shipped in interstate commerce on or about November 11 and December 9, 1941, by the Don Gilmore Laboratories, Inc., from Cleveland, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate."

Analysis of a sample of the article showed that each powder contained 6.93 grains of acetanilid, 2.61 grains of caffeine citrate, and 2.50 grains of sodium bicarbonate.

It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess.

It was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Directions: Place a powder on the tongue and swallow with water. Repeat in twenty minutes if necessary," since when taken in accordance with these directions the powders would provide for the administration of slightly less than 14 grains of acetanilid in 20 minutes. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the powders contained acetanilid and the labeling contained no warning that frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug; and, further, that the powders should not be given to children. (3) In that the label failed to bear adequate directions for use. (4) In that the statement on the label, "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate," was false and misleading.

On July 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[3]

756. Adulteration of triple distilled water and sterile solution of epinephrine chloride; misbranding of Suppletive Formula No. 1, Sterile Supportive Formula S. G. M. a., Sterile Solution Formula No. 1, Compressed Tablets No. 358, and Compressed Tablets Thyroid; adulteration and misbranding of Neohormestrin, solution of quinine and urea hydrochloride, quinine sulfate tablets, and sterile solution of ovarian extract. U. S. v. E. S. Miller Laboratories, Inc. Plea of nolo contendere. Fine, $75 on each of 4 counts. Imposition of sentence suspended on remaining counts and defendant placed on probation for 1 year. (F. D. C. No. 4132. Sample Nos. 7368–E, 7397–E, 7655–E, 7939–E, 30843–E, 31909–E, 31912–E, 32631–E, 53828–E to 53831–E. incl., 53833–E, 55734–E.)

This case involved the following violations and products: Failure to bear adequate directions, adequate warning statements, and satisfactory ingredient statements, Suppletive Formula No. 1 and Sterile Solution No. 1; failure to bear adequate directions and warnings, Compressed Tablets No. 358 and Compressed Tablets Thyroid; failure to bear adequate directions and ingredient statements, Sterile Supportive Formula S. G. M. a.; failure to comply with own standard of strength and quality and to bear satisfactory ingredient statement, Neohormestrin; failure to comply with official standard and reduction of quality because of the presence of minute particles of rubber, triple distilled water; failure to comply with official standards of strength and quality, quinine and urea hydrochloride, quinine sulfate, and epinephrine chloride.

[3] See also Nos. 754, 755.